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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/479,997	06/07/1995	DEAN ENGELHARDT	ENZ-5(D6)(C2	8799
28171	7590	07/14/2004	EXAMINER	
ENZO BIOCHEM, INC. 527 MADISON AVENUE (9TH FLOOR) NEW YORK, NY 10022			MARSCHER, ARDIN H	
			ART UNIT	PAPER NUMBER

1631

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

921-  
**Office Action Summary**

Application No.

08/479,997

Applicant(s)

ENGELHARDT ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 826-1227 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 826-1227 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/4/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/29/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicants' arguments, filed 5/7/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **NEW MATTER**

Claims 826-1227 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER has been newly added to the claims due to the added "non-nucleotidyl" limitation directed to Sig moiety species. Applicants have not pointed to written basis as filed for this limitation nor has written basis as filed been found via consideration of the entirety of the instant disclosure as filed. It is acknowledged that numerous types of Sig moieties have been exemplified as filed, however, a clear delineation of such moieties to support the "non-nucleotidyl" limitation has not been found. All independent claims contain this NEW MATTER limitation. Claims which depend from independent claims either directly or indirectly also contain this NEW MATTER due to their dependence. This rejection is necessitated by amendment.

### **VAGUENESS AND INDEFINITENESS**

Claims 826-1227 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims as presently pending continue to cite analogs with various characteristics directed to DNA or RNA incorporation and also characterized as not substantially interfering with double helix formation or nucleic acid hybridization. The metes and bounds of the chemical structure of such characterized analogs has not been set forth and thus is still vague and indefinite as to what metes and bounds of such analog chemical structures correspond to the above noted characteristics. All independent claims contain these unclear limitations. Claims which depend from independent claims either directly or indirectly also contain this unclarity due to their dependence. This rejection is necessitated by amendment.

The vagueness and indefiniteness set forth in the previous office action, mailed 11/26/03, directed to the conflict between independent claims citing deoxy-type oligomers or polydeoxynucleotides vs. dependent claims requiring a ribonucleotide in the claimed composition is reiterated from the previous office action as still a conflict in the newly added claims. This is an issue in dependent claims 855, 886, 920, 955, 987, 1020, 1053, 1086, 1120, 1154, 1188, and 1125 vs. respective independent claims or internally within the claims wherein a polydeoxyribonucleotide, for example, further comprises a ribonucleotide or vice versa.

. This rejection is necessitated by amendment.

### SCOPE OF ENABLEMENT REJECTION

Claims 956-987 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleotide containing embodiments wherein the sugar is a furanose moiety, such as ribose or deoxyribose, does not reasonably provide enablement for any generic sugar, such as cited in claim 956 etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

This rejection is maintained and reiterated from the previous office action, mailed 11/26/03, regarding claims still broadly citing sugar SM moieties directly or via

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dependence. This rejection has not been argued and is therefore maintained for reasons of record.

### **PRIOR ART**

The non-nucleotidyl limitation for the instant Sig moieties in the presently pending claims prevents a prior art rejection based on Dunn et al. [Cell 12:23 (1977)] or Hung (P/N 4,224,408), but removal of the NEW MATTER regarding such a limitation would require re-application of such a rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 888, 890, 898, 903, 905, 907, 911, 919, 921, 923, 930, 931, 936, 937-939, 941, 943, 945, 951, 954, 956, 964, 965, 971, 972, 974, 978, 986, 988, 996, 997, 1002-1005, 1007, 1010, 1011, 1019, 1022, 1031, 1036-1038, 1043, 1044, 1052, 1054, 1062, 1063, 1068-1071, 1073, 1075, 1077, 1085, 1156, 1158, 1165, 1166, 1171-1173, 1175, 1177-1179, 1187, 1191, 1193, 1200, 1201, 1206-1208, 1211, 1214, 1215, 1221, and 1224 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Hartmann et al. [Biopolymers 20:2635 (1981)].

The azo label previously disclosed in Hartmann et al. is still a non-nucleotidyl etc. Sig moiety. Therefore, this rejection is reiterated and maintained from the previous office action, mailed 11/26/03, and as necessitated by amendment regarding newly added claims.

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No claim is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

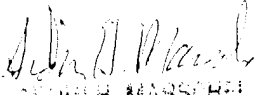
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

July 12, 2004

  
ARDIN H. MARSCHEL  
7/12/04